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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
YANG, NELSON C	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/970,434	PETERSEN ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 22 October 2002 .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 5, and 16-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilding et al [US 5,955,029].

Wilding et al teaches a cartridge having a sample flow path (claim 1), a lysing chamber containing at least one filter (claim 2), a waste chamber in fluid communication with the lysing chamber (column 13, lines 13-16), which has an external surface (figures 1, 2), a third chamber (PCR chamber) connected to the lysing chamber via an analyte flow path for receiving the analyte separated from the sample(claims 1-4), and a flow controller (claims 2, 3).

The limitation "an external surface for contacting the transducer to sonicate the lysing chamber" is considered an intent of use, and therefore, no patentable weight is given to this limitation.

3. With respect to claims 2 and 3, Wilding teaches a cartridge with a nesting site for holding fluid input, a PCR chamber for receiving polynucleotides and PCR reagents, and a detection chamber in fluid communication with the PCR chamber (claim 4).

4. With respect to claim 5, Wilding et al teaches a means for thermally regulating the contents of said chamber whereby the temperature is controlled to amplify said preselected polynucleotide (claim 8) and at least one optical detector for detecting the analyte (column 4, lines 46-62).

5. With respect to claims 16-20, Wilding et al discloses a device for isolating and amplifying a polynucleotide in a sample. Specifically, Wilding et al teaches that binding moiety may be immobilized on a wall of a flow channel or solid phase particles which bind a particular type of cells in a heterogeneous cell population prior to lysis. And, after lysis, complex forming agents, such as magnetic beads coated with a polynucleotide probe may be provided within the mesoscale flow system to capture and amplified the polynucleotide. (column 5, lines 20-53, column 11, lines 15-23). Wilding et al also discloses the use of different filters (figures 8 and 14, column 15, example 2). Wilding et al teaches the use of filters for filtering cell debris after lysis and prior to amplification, and a sieve for separating cells by size upstream from the analysis chamber. (column 13, line 41 - column 14, line 13).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029] in view of Murphy et al [US 5,374,522].

Wilding et al teaches the use of magnetic beads for binding to the analyte, which includes virus and other cell types (column 3, lines 58-62, column 13, lines 1-5). Wilding does not teach the use of beads for rupturing the cells or viruses (column 5, lines 28-40). Murphy et al, however, teaches that prior art methods for extracting RNA or DNA from refractory bacteria can create excessive heat which has deleterious effects on the genetic cellular constituents such as DNA and RNA, rendering them unusable in subsequent diagnostic procedures (column 4, lines 26-64). Other methods are time consuming, expensive, difficult to use safely and efficiently (column 5, lines 20-25). Murphy et al further teaches that the low power density of the ultrasound bath with beads while sufficient to disrupt cells is not powerful enough to destroy RNA or DNA once released (column 5, lines 5-20). Therefore it would be obvious to use beads to rupture cells, as taught by Murphy et al, in the cartridge of Wilding et al in order to disrupt cells without destroying the RNA or DNA once released.

8. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029], in view of Nelson et al [US 5,660,029].

Wilding et al teaches a cartridge with a reaction chamber for amplifying the analyte (claim 3, 4) and gel electrophoresis area (column 4, lines 46-62). Wilding does not specifically teach the use of a capillary electrophoresis area. Nelson et al, however, teaches that benefits of capillary electrophoresis include rapid run times, high separation efficiency, small sample volumes, etc. Nelson et al further teaches that although CE was originally carried out in capillary tubes, of increasing interest is the practice of using microchannels or trenches of capillary dimension on a planar substrate, known as

microchannel electrophoresis (MCE) (column 1, lines 8-40). Therefore it would be obvious to use a capillary electrophoresis area, as taught by Nelson et al, in the cartridge of Wilding et al, in order to obtain rapid run times, high separation efficiency, and small sample volumes.

9. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029] in view of Carlin [*Ultrasonics*, 1960, McGraw-Hill].

Wilding et al does not specifically teach the use of a wall that is dome-shaped and convex. However, it would obvious to a person of ordinary skill in the art to use a wall that is dome-shaped and convex, as Carlin teaches the design of plastic lenses from glass, metals, and plastics such as plexiglass or polystyrene, in order to focus beams, which would be very valuable for agitational work, where a great amount of ultrasonic output is necessary (p. 89-90, 61-63). Therefore it would be obvious to use a wall that is dome-shaped and convex, as taught by Carlin, in the cartridge of Wilding et al, in order to focus beams, where a great amount of ultrasonic output is necessary.

10. With respect to claim 9, the Wilding et al teaches a device where the device ranges from microns to a few millimeters in thickness (column 4, lines 55-60).

11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029] in view of Bersted et al [US 6,129,879].

Although Wilding et al does not specify a wall comprised of a sheet or film of polymeric material, it is common to find PCR devices comprised of polymeric material such as polypropylene, since the surface of polypropylene is smooth and inert so does not readily bind enzymes and allows for easy recovery of products. Furthermore, Bersted et

al teaches that other advantages of polypropylene include low cost, ease of processing, strength, chemical inertness and hydrophobicity (column 1, lines 35-44). Therefore, it would be obvious to use a wall comprised by a sheet or film of polymeric material, as taught by Bersted et al, since the surface of polymeric material does not readily bind to enzymes and allows for easy recovery of products.

12. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al [US 5,955,029] in view of Lynnworth [US 4,335,719].

Although Wilding et al does not teach the use of stiffening ribs, it would be obvious to a person of ordinary skill in the art to use them, as evidenced by Lynnworth, who teaches that in order to increase the transmission through the shield at higher frequencies, or to reduce the mass of the shield, the shield thickness may be reduced considerably. Tube wall thickness as small as 0.1 mm are commonly available for many engineering materials. However, such thin walled tubes are not always adequate structurally, as their reduced stiffness is subject to vibratory motion. Therefore the thin shield is reinforced or stiffened in one direction by ribs (column 12, lines 20-30). Therefore, it would be obvious to use stiffening ribs, as taught by Lynnworth, inorder to increase the transmission through the wall at higher frequencies.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-3, 5, 8, 9, 12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 50 of U.S. Patent No. 6,440,725. Although the conflicting claims are not identical, they are not patentably distinct from each other because there share the same elements. The prior art teaches a device for use with an ultrasonic transducer to separate an analyte from a fluid sample, the device comprising a cartridge having a first flow path including a lysing chamber for lysing sample components to release the analyte therefrom, wherein the lysing chamber contains a membrane or filter for capturing the sample components as the

sample flows through the lysing chamber, and wherein the lysing chamber is defined by at least one wall for contacting the transducer to effect the transfer of ultrasonic energy to the lysing chamber; at least a first waste chamber, downstream of the extraction chamber, for receiving waste fluid; an extraction chamber, downstream of the lysing chamber, the extraction chamber containing at least one solid support for capturing the released analyte; and at least one flow controller for directing the waste fluid into the waste chamber and for directing the eluted analyte into the second flow path (claims 1-8).

15. With respect to claims 2 and 3, the device further includes a reagent chamber fluidicly connected to the extraction chamber via a second flow path, and a reaction chamber for receiving the eluted nucleic acid via the second flow path and for holding the nucleic acid for the amplification reaction, wherein the portion of the cartridge defining the reaction chamber protrudes from the rest of the cartridge body (claims 8, 50).

16. With respect to claims 8 and 9, the prior art teaches that the wall of the lysing chamber comprises a polymeric material, and wherein the wall has a thickness in the range of 0.01 to 0.5 mm (claim 48).

17. With respect to claim 12-14, the device taught in the prior art also comprises beads in the lysing chamber for rupturing the sample components (claim 2), and at least one solid support in the extraction chamber is selected from the group consisting of filters, beads, fibers, membranes, glass wool, filter paper, polymers and gels (claim 3).

Conclusion

18. No claims are allowed.

19. The following references are also cited as art of interest: Hikita et al [US 5,122,993], Taylor et al [US 6,431,476], and Rolle et al [5,993,872].

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is 703-305-4508. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

NY

LONG V. LE
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6/20/03